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DK

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|---|---|---|---|
| 08/349,177 | 12/02/94 | GREY H | 14137-58-4 |

020350 HM12/1105
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| EXAMINER | |
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| SCHWADRON, R | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1644 | 31 |

DATE MAILED: 11/05/99

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

| Office Action Summary | Application No. 08/349,177 | Applicant(s) Grey et al. |
|---|---|---|
| | Examiner Ron Schwadron, Ph.D. | Group Art Unit 1644 |

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *1* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

**Disposition of Claims**

☒ Claim(s) *56-127* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *56-127* are subject to restriction or election requirement.

**Application Papers**

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

*--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---*

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 56-58,61-83,85-87,90-104,106,107,110-121,123,126,127 are drawn to peptide compositions classified in Class 514, subclass 2.

II. Claims 59,60,88,89,108,109,124,125 are drawn to nucleic acid compositions classified in Class 536, subclass 23.1. While the claims recite that the aforementioned are compositions containing an immunogenic peptide, said claims do not recite an immunogenic peptide, they are actually drawn to nucleic acid compositions.

III. Claims 84,105,122 a method of inducing a CTL response, classified in Class 424, subclass 193.1.

2. Inventions I and II are different products. These products are chemically, structurally and functionally distinct. These products have different art recognized uses. Therefore they are novel and unobvious in view of each other and are patentably distinct.

3. Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product could be used to detect CTL in an in vitro assay.

4. The nucleic acids compositions of invention II are not used in the method of invention III. Therefore they are novel and unobvious in view of each other and are patentably distinct.

5. Because these inventions are distinct for the reasons given above and the search required for any group from Groups I-III is not required for any other group from Groups I-III and Groups I-III have acquired a separate status in the art as shown by their different classification and divergent subject matter, restriction for examination purposes as indicated is proper.

6. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

7. Applicant is required to elect the following species (as they pertain to the elected invention).

8. This application contains claims directed to the following patentably distinct species of the claimed invention:

a) a peptide that comprises an epitope consisting of 8 residues

b) a peptide that comprises an epitope consisting of 9 residues

c) a peptide that comprises an epitope consisting of 10 residues

d) a peptide that comprises an epitope consisting of 11 residues

These peptides are different in that they are of different lengths.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

9. Upon selecting a peptide from a-d from the requirement enunciated in the previous paragraph of this Office Action, a further election of species is required.

The claims are generic to a plurality of disclosed patentably distinct species comprising any particular set of peptides which is encompassed by a particular formula recited in the claims. Such species would be a peptide with a first conserved residue at the second position from the N-terminus where the amino acid was A and a second conserved residue at the C-terminal wherein the amino acid was M (eg. the peptide of claim 56 wherein one amino acid from each Markush group recited in the claim is elected). Applicant needs to select one species for examination (eg. A at first specified position, M at second specified position). These peptides are structurally and functionally distinct and encode peptides that are structurally and functionally distinct, and derived from different proteins with different functions.

Applicant is required to elect a species of peptide from one of the peptides recited in Table 3 or 4. Said species should be encompassed by the elected motif formula above (eg. if applicant elects a nine amino acid peptide with A at position one and M at position two, then the peptide elected from Table 3 should have the aforementioned characteristics). Furthermore, said peptide also needs to be consistent with all other elected species chosen by applicant (eg. if applicant elects

the cancer antigen p53, then the elected peptide needs to be a p53 derived peptide).

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species, even though this requirement is traversed.

10. Upon selecting a peptide from the requirement enunciated in paragraphs 8 and 9 of this Office Action, a further election of species is required. This application contains claims directed to the following patentably distinct species of the claimed invention:

a) a peptide comprising an immunogenic epitope not linked to another molecule

b) peptide attached to a lipid

c) a peptide attached to a T helper epitope

d) a peptide attached Pan DR epitope

e) a peptide attached to a CTL epitope

f) a peptide linked to a carrier

These peptides are structurally and functionally distinct and encode peptides that are structurally and functionally distinct, and derived from different proteins with different functions.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

11. Upon selecting a peptide species above, a further election of species is required. This application contains claims directed to the following patentably distinct species of the claimed invention:

a) peptide encoding cancer associated antigen

b) pathogen derived peptide

These peptides are structurally and functionally distinct and encode peptides that are structurally and functionally distinct, and derived from different proteins with different functions.

If applicant elects a), applicant needs to elect one of the following species

(1)HER2/neu

(2)p53

(3)MAGE

(4)prostate

If applicant elects b), applicant needs to elect one of the following species
(1)HIV
(2)HBV
(3)HCV
(4)HPV
(5)malaria
These peptides are structurally and functionally distinct and encode peptides that are structurally and functionally distinct, and derived from different proteins with different functions.

12. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.
Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

13. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official

Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Group 1600 at (703) 308-4242.

14. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Monday through Thursday from 7:30 to 6:00. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Ms Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Ron Schwadron, Ph.D.
Primary Examiner
Art Unit 1644
November 4, 1999

RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP ~~1800~~ 1600